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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,540	02/26/2004	Urs Jorimann	032498-023	3251

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EXAMINER
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SHERR, CRISTINA O

ART UNIT	PAPER NUMBER
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3621

MAIL DATE	DELIVERY MODE
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08/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,540	<b>Applicant(s)</b> JORIMANN ET AL.	
	<b>Examiner</b> Cristina Owen Sherr	<b>Art Unit</b> 3621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,24-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This communication is in response to applicant's amendment filed May 18, 2007.

Claims 1-2 and 4-19 are pending in this case.

#### ***Election/Restrictions***

2. Applicant's election with traverse of claims 1,2 and 4-19 in the reply filed on May 18, 2007 is acknowledged. The traversal is on the ground(s) that the additional authentication is being interpreted by the examiner as a different identification technique. This is not found persuasive because even if the technique is the same, you either have one step or two steps to identification or authentication, and you can't simultaneously have one step and two steps. Thus, the species are mutually exclusive.

3. The requirement is still deemed proper and is therefore made FINAL.

#### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1-2 and 4-19 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaung et al (US 6,446,069).

7. Regarding claim 1 –

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Yaung discloses a method for controlling electronic records produced by an application software program, wherein designated users performing use the program and apparatus assigned user roles, said method comprising:

- (a) restricting access to the application software program to the designated users through a user authentication;
- (b) assigning a set of user rights to each user role, wherein said designated users are divided into a first group of users who are given a right to sign the electronic records and a second group who are denied the right to sign the electronic records and authenticating the electronic records by means of at least one electronic signature by one of the users of the first group, wherein access to step
- (c) storing the electronic records in a protected data file format; (d) maintaining a history of access entries and activities performed in the application software program; and
- (e) wherein access is denied to the users from the second group. (e.g. col 5 ln 58-66, col 6 ln 30-58, col 9 ln 1- col 10 ln 11, col 8 ln 23-45).

8. Although Yaung does not specifically deal with medical records as in the instant application, it would be obvious to adapt the teaching of Yaung to any type of software available electronically.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaung et al (US 6,446,069) in view of "Title 21, CFR Part 11 - Electronic Records; Electronic Signatures".

10. It would be obvious to combine Yaung and CFR part 11 in order to comply with one arbitrary set of rules rather than another.

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11. Claims 4-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaung et al (US 6,446,069).

12. Regarding claims 4-10 –

Yaung discloses wherein the at least one electronic signature comprises a plurality of electronic signatures, wherein a signature meaning is attached to each of said plurality of electronic signatures, said signature meaning being selected from a list of signature meanings, wherein the signature meaning indicates a signature status that an electronic record will have as a result of an electronic signature, and wherein each signature meaning in said list is correlated with a signature level in a hierarchy ascending from a lowest to a highest signature level, so that each of said plurality of electronic signatures is hierarchically ranked by way of its attached meaning; wherein the hierarchically ranked meanings include at least one of the meanings "Tested", "Reviewed", "Approved", and "Released"; wherein each user of the first group is assigned a maximum signature level that is selected from the signature levels in said list, and wherein said user is not allowed to attach to his/her signature a signature meaning that exceeds said user's assigned maximum signature level; wherein said maximum signature level is assigned to a user in accordance with the user role performed by said user; wherein when the electronic record has already been signed at least once, said user is not allowed to attach to his/her signature a signature meaning that ranks lower than the signature status which the electronic record has as a result of said at least one previous signature; wherein when the electronic record has already been signed at least once, said user is not allowed to attach to his/her signature a signature meaning that

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does not rank at least one level higher than the signature status which the electronic record has as a result of said at least one previous signature; wherein said user is only allowed to attach to his/her signature a signature meaning exactly one level higher than the signature status which the electronic record has as a result of said at least one previous signature, so that said plurality of signatures follow each other in consecutive ascending order of signature level (e.g. col (col 5 ln 58-66, col 9 ln 1-c0l 10 lm 11, col 7 ln 35-59, col 8 ln 23-45).

13. As above, although Yaung does not specifically deal with medical records as in the instant application, it would be obvious to adapt the teaching of Yaung to any type of software available electronically.

14. Regarding claims 11-12 –

Yaung discloses the method wherein a record is fully authenticated after a prescribed number of signatures comprising at least two different signature levels have been attached to said record; wherein the at least two different signature levels comprise a prescribed hierarchically ascending series of signature levels (e.g. col 7 ln 35-59, col 8 ln 23-45).

15. Regarding claim 13 –

Yaung discloses the method wherein step (e) comprises attaching a remark to the electronic signature (e.g. col 7 ln 60 – col 8 ln 67).

16. Regarding claims 14 – 15 –

Yaung discloses the method wherein the signature levels attached to the signature meanings in said list from the lowest to the highest level are consecutive ascending

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numbers starting at the number one; wherein the signature levels attached to the signature meanings in said list from the lowest to the highest level are nonconsecutive ascending numbers, leaving unused numbers available for additional intermediate signature levels (e.g. col 7 ln 35-59, col 8 ln 23-45).

17. Regarding claims 16-17 –

Yaung discloses the method of claim 6, wherein parts (a) and (b) of the method are performed by a system administrator; wherein said parts (a) and (b) include at least one of: assigning user names and passwords to the designated users, retiring said user names and passwords, assigning the maximum signature level to each user account, and defining the signature meanings and ranking them according to signature levels (e.g. col 7 ln 35-59, col 8 ln 23-45).

18. Claims 18-19 are rejected under the same criteria as above.

19. Examiner's note: Examiner has cited particular columns and line numbers in the references as applied to the claims above for the convenience of the applicant.

Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may be applied as well. It is respectfully requested from the applicant, in preparing the responses, to fully consider the references in entirety as potentially teaching all or part of the claimed invention as well as the context of the passage as taught by the prior art or disclosed by the examiner.

### ***Conclusion***

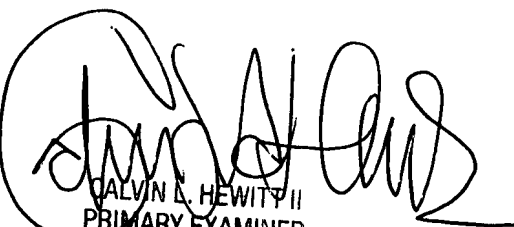
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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cristina Owen Sherr whose telephone number is 571-272-6711. The examiner can normally be reached on 8:30-5:00 Monday through Friday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Fischer can be reached on 571-272-6779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Cristina Owen Sherr  
Patent Examiner, AU 3621

  
CALVIN L. HEWITT II  
PRIMARY EXAMINER